

DMB

Display Date	11-2-99
Expiration Date	11-3-99
Certifier	SNR ere

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Training Programs for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is initiating of two new training programs: The Regulatory Project Manager Site Tours and the Regulatory Project Manager Shadowing Program. These programs are intended to give the Center for Drug Evaluation and Research's (CDER's) regulatory project managers an opportunity to tour pharmaceutical facilities and shadow their industry counterparts. Both the tour and shadowing programs are intended to enhance review efficiency and quality by providing CDER staff with a better understanding of the pharmaceutical industry and its operations. The purpose of this notice is to invite pharmaceutical companies interested in participating in these programs to contact CDER for more information.

DATES: Pharmaceutical companies may request training program information at any time.

FOR FURTHER INFORMATION CONTACT: Deborah L. Kallgren, Center for Drug Evaluation and Research (HFD-2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-548 1, FAX 301-827-3 132.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high

performance in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is initiating two new training programs to give regulatory project managers the opportunity to tour pharmaceutical facilities and shadow their industry regulatory/project management counterparts. The goals are: (1) To provide first hand exposure to industry's drug development processes, and (2) to provide a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. The Project Manager Site Tours and Regulatory Project Manager Shadowing Program

A. Regulatory Project Management Site Tours

In this program, over a 2-day period, small groups (six or less) of project managers accompanied by a senior level regulatory project manager may observe operations of pharmaceutical manufacturing, packaging facilities and pathology/toxicology laboratories, and regulatory affairs operations. The purpose of this tour, or any part of the program, is meant to improve mutual understanding and to provide an avenue for open dialogue.

B. Regulatory Project Manager Shadowing Program

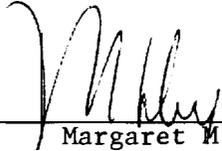
In this program, over a 2- to 3-day visit, regulatory project managers will accompany their industry counterparts in their day-to-day activities. The primary objective of the shadowing program is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, project tracking mechanisms, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management and team techniques and processes employed by the pharmaceutical industry, professional and personal growth, and enhanced job satisfaction and performance through increased understanding of the industry processes and procedures that directly relate to their jobs.

C. Site Selection

All travel expenses associated with the site tours and/or shadowing programs will be the responsibility of CDER, therefore, selection of potential facilities will be based on available resources for this program.

If your firm is interested in learning more about these training opportunities, please contact Deborah L. Kallgren (address above).

Dated: 10/25/99
October 25, 1999



Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

